iVascular®

therapies for living

essential

Paclitaxel eluting coronary balloon dilatation catheter

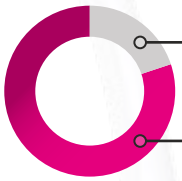
Safe & Accurate
local drug delivery

CARDIO

www.ivascular.global

effectiveness based on **proprietary technology TransferTech**

1



Excipient | **20 %**

Paclitaxel | **80 %**

+ volatile solvent

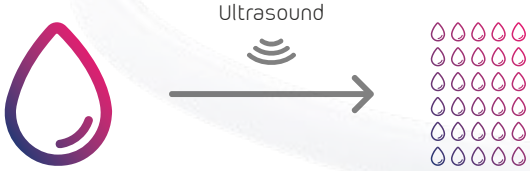
Excipient

- Organic ester
- Biocompatible
- Lipophilic

Paclitaxel

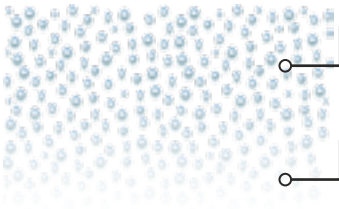
- Lipophilic
- Inhibition of stenosis
- Specific cellular receptors

2



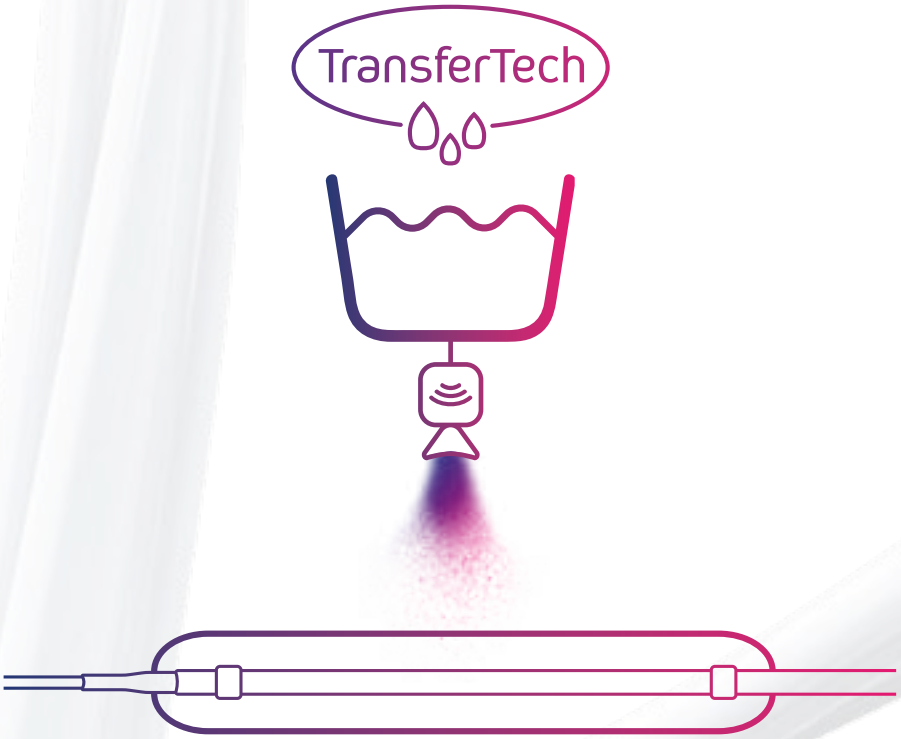
Spray Technology

Dosage of uniform diameter nanodrops by ultrasonic deposition



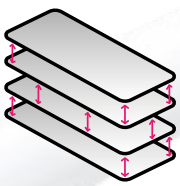
Uniform coating

Homogeneous drug dose



3 Multi-layer technology

- **Coating durability during the procedure**
- **No cracking**



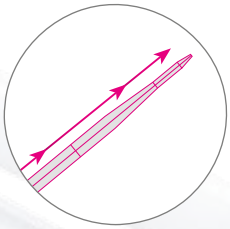
4 Dry-off

- **Microcrystalline structure**
- **Optimal drug transfer to the vessel wall within 30-60 seconds**

last balloon technology

The best tip profile

The lowest tip profile for **perfect crossability**



Smooth transition

Optimized design for excellent **pushability** and **flexibility**

Tungsten based polymeric Radiopaque Marker

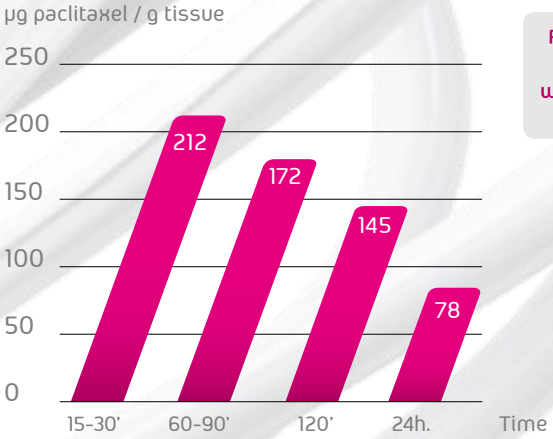
Great **flexibility** with optimal **visibility**

preclinical efficacy

High antiproliferative efficacy and prevention of restenosis

- **>50% less restenosis** than Control
- **23% less restenosis than other DEBs**

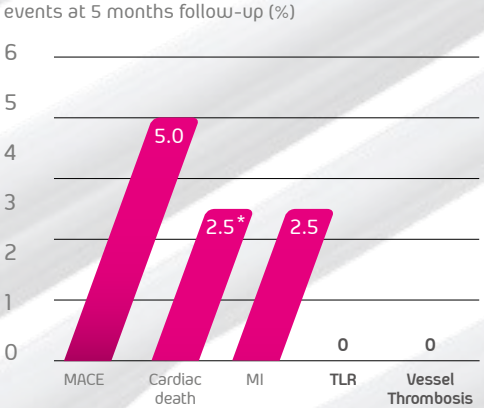
Preclinical study N = 17. Angiographical and histological follow-up 28 days. Tests made by iVascular. Data stored on file at iVascular.



Rapid release of paclitaxel with long-term efficacy

Pharmacokinetic study. Tests made by iVascular. Data stored on file at iVascular.

clinical safety



DEB observational registry by J.Benezet
5 month clinical results (N=38)

The treatment of de novo coronary lesions with the Essential® DEB.

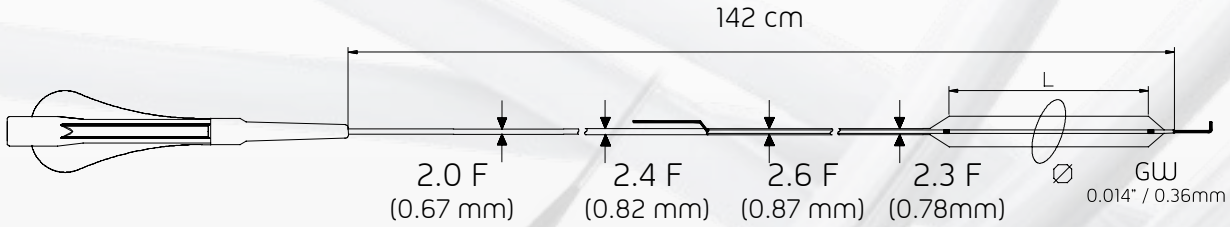
The Essential® DEB system demonstrated:

- Safety (2.5% death / 2.5% MI)
- Efficacy (0% TLR)
- Procedure success: 100%

*One patient with atrial fibrillation died after 41 days follow up due to intracranial hemorrhage associated with antithrombotic therapy.

essential features

- **Rapid exchange catheter (RX)**
- Guide wire compatibility: **max. 0.014"**
- Tip profile: **0.016"**
- Crossing profile: from **0.021"** up to **0.027"**
- Nominal pressure: **6 atm**
- RPB: **16 atm** / ABP: **20 atm**
- **2 polymeric markers** of high flexible tungsten base



Product with CE mark, certified by Notified Body 0318

Balloon diameter (mm)	Working catheter length: 142 cm					
	Stent length (mm)					
	10	15	20	25	30	40
1.50	BC DPR14 150 150 010	BC DPR14 150 150 015	BC DPR14 150 150 020	-	BC DPR14 150 150 030	-
2.00	BC DPR14 150 200 010	BC DPR14 150 200 015	BC DPR14 150 200 020	BC DPR14 150 200 025	BC DPR14 150 200 030	BC DPR14 150 200 040
2.25	BC DPR14 150 225 010	BC DPR14 150 225 015	BC DPR14 150 225 020	BC DPR14 150 225 025	BC DPR14 150 225 030	BC DPR14 150 225 040
2.50	BC DPR14 150 250 010	BC DPR14 150 250 015	BC DPR14 150 250 020	BC DPR14 150 250 025	BC DPR14 150 250 030	BC DPR14 150 250 040
2.75	BC DPR14 150 275 010	BC DPR14 150 275 015	BC DPR14 150 275 020	BC DPR14 150 275 025	BC DPR14 150 275 030	BC DPR14 150 275 040
3.00	BC DPR14 150 300 010	BC DPR14 150 300 015	BC DPR14 150 300 020	BC DPR14 150 300 025	BC DPR14 150 300 030	BC DPR14 150 300 040
3.25	BC DPR14 150 325 010	BC DPR14 150 325 015	BC DPR14 150 325 020	BC DPR14 150 325 025	BC DPR14 150 325 030	BC DPR14 150 325 040
3.50	BC DPR14 150 350 010	BC DPR14 150 350 015	BC DPR14 150 350 020	BC DPR14 150 350 025	BC DPR14 150 350 030	BC DPR14 150 350 040
3.75	BC DPR14 150 375 010	BC DPR14 150 375 015	BC DPR14 150 375 020	BC DPR14 150 375 025	BC DPR14 150 375 030	BC DPR14 150 375 040
4.00	BC DPR14 150 400 010	BC DPR14 150 400 015	BC DPR14 150 400 020	BC DPR14 150 400 025	BC DPR14 150 400 030	BC DPR14 150 400 040
4.50	BC DPR14 150 450 010	BC DPR14 150 450 015	BC DPR14 150 450 020	BC DPR14 150 450 025	BC DPR14 150 450 030	BC DPR14 150 450 040

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Manufactured by:

LVD Biotech, S.L.
www.ivascular.global
info@ivascular.global

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